

Reissue of U.S. Patent No. 5,878,745
Copy of Specification Pursuant to 37 C.F.R. §1.173(a)(1)

7

the distal end of the mask, the collapse of ring 18 is operative upon the formed distal-end opening 43 of tube 26 to somewhat flatten the opening 43, into a generally shovel-shaped distal lip feature which merges smoothly into the adjacent upwardly dished double-wall. shape 18' shown in the longitudinal mid-section of FIG. 9.

It will be appreciated that the GLM device described thus far has an airway tube 11 that is of larger diameter than the evacuation tube 23; in this circumstance, the airway tube 11 is large enough to accommodate guided insertion of an endotracheal tube. The tubes 11, 23 enter the described laryngeal mask 10 in side-by-side relation and are preferably adhesively secured to each other in this side-by-side relation, and along their full longitudinal extent, in order to provide a measure of torsional resistance against twisting, thereby aiding a medically qualified person in quickly and correctly installing a fully deflated-GLM in a patient, with assurance that, upon inflation of ring 18 and the back-cushion panel 25, an exclusive and sealed airway connection will be established to the laryngeal inlet, via lumen 14 and from the airway tube 11; concurrently, a similarly exclusive evacuation connection is established to the upper sphinctral region of the oesophagus, via the distal-end opening 43 of tube 26, through the evacuation tube 23, and to suitable waste-collection means (not shown) external to the patient.

More specifically as to insertion of the fully deflated GLM device in a patient, it will be understood that a range of GLM sizes is available from which to select a sufficiently correct size for the patient. Deflation is accomplished via external means (not shown) and via check-valve means 21 to hold the deflated condition wherein the dome shape of body member 13 rises from within the dished peripheral lip 18' of the collapsed ring 18. A skilled operator is quickly able to develop the desired appearance of the GLM in its deflated state; but for a uniformly correct deflated shaping, it is recommended to use a forming tool as described in U.S. Pat. No. 5,711,293.

When correctly shaped and in its deflated condition, and at the distal end of the GLM, the opening 43 will have been flattened, and this distal end merges with the peripheral lip 18' of the collapsed ring 18. Noting that the entire distal half of the mask is of relatively soft material, stiffened only by indicated adhesive connection, the distal end projects distally and at its upwardly flared merge with lip 18', for low acute-angle incidence to the posterior arcuate profile of the patient's throat passage. That being the case, a medical technician need only make sure that upon inserting the mask via the patient's mouth and throat, the flattened distal end rides the outer (posterior) arcuate contour of the patient's airway, in that the softly flexible nature of the distally projecting and somewhat flattened distal end will be flexibly self-adapting to local irregularities (if any) in the course of passage into the pharynx; final insertional location is noted by an increase in encountered resistance, upon distal-end engagement of the GLM with the upper sphinctral region of the oesophagus. At this juncture, inflation air supplied via line 19 and retained by check-valve means 21 establishes (i) the described seal of ring 18 to the laryngeal inlet, (ii) back cushion (panel 25) contact with the back wall of the pharynx, and (iii) full opening of the evacuation tube 26 for maximum accommodation of a possible gastric discharge from the oesophagus.

Beyond what has been described, FIG. 10 illustrates at phantom outline 26' that the flexible length of the re-entrant tube 26 may be of even greater length than the approximately half-mask length shown by the solid lines of FIG. 5. In that event, arcuate stiffener ridges as described at 42 will

8

be preferred, as long as lateral support is needed to prevent side-wall collapse of the extended tube 26', in the inflated condition of the mask, i.e., including inflation of back-cushion panel 25.

FIGS. 10 to 12 illustrate another GLM embodiment wherein an airway tube 50 and an evacuation tube 51 are of equal size, adhered (as suggested at 52) to each other in side-by-side relation for torsionally resistant and symmetrically positioned entry into corresponding side-by-side ports 53, 54 of the dome like moulded backing plate 55 or body member of FIGS. 11 and 12. The backing plate 55 may be similar to plate 13 of FIG. 4, except that in FIG. 11 the somewhat helically arcuate conduit path from the inserted distal end of evacuation tube 51 to the point 56 of softly compliant re-entrant tube (26) connection is provided by an integral passage formation 57 of the backing plate 55. At point 56 in FIG. 11, the formation 57 is seen to be in the central vertical plane 58 of symmetry of the bowl of backing plate 55 and in alignment for accepted proximal-end insertional accommodation of a re-entrant tube 26 of thin-walled material to which backing plate 55 is to be assembled, with edges of the straight slot 38' supporting tube 26 in the manner already described. Also integrally formed with backing plate 55 is an inlet-connection counterbore for coupled connection of airway tube 50 to the laryngeally exposed side of the mask. Features in FIG. 10, such as the back-cushion panel 25, the inflatable ring 18, and the adhesively bonded connection 39 of panel 25 to tube 26 are all as previously described.

It will be understood that the inside-out technique described in connection with FIGS. 5 and 6 for initially moulding and then inverting the skirt of the moulded product, is but one illustration of a way to create the mask and its inflatable ring, in which case the flexible drainage conduit does not get inverted. That being the case, the reinforcement ribs 42 are initially formed portions of the outer surface of the moulded product. On the other hand, another technique for forming the mask with its inflatable ring, involves moulding the mask bowl integrally with an elliptically configured product as shown in FIG. 13, wherein completion of inflatable-ring (18) integrity requires only an adhesively bonded completion of the ring peripherally around the inner substantially elliptical profile, where backing-plate (13) connection is also adhesively secured. In that case, the drainage tube 26 is integrally-moulded with the non-invertible ring (18), so that an inversion of tube 26 is necessary, to have it project re-entrantly, in the proximal direction, and the moulded product which is to become inflatable ring 18 must be cut away as at 40, to permit inverted tube 26 to "pass through" the inflatable ring, in order to develop a relationship which is suggested by FIG. 5. Of course, if tube 26 is to be inverted, the reinforcement ribs 42 are preferably integrally formed as radially inward rib reinforcements or discontinuities in the moulded bore of tube 26. Inversion of tube 26 places these rib reinforcements on the outer surface of tube 26, so that the bore of tube 26 is inherently smooth.

What is claimed is:

1. A laryngeal mask construction for concurrent airway service to a patient's laryngeal inlet and for removal of gastric-discharge products from the oesophagus, said construction comprising:

an inflatable ring in the form of a generally elliptical annulus having an outer periphery configured for continuously sealed adaptation to the laryngeal inlet, said ring extending longitudinally between proximal and distal ends and having an inflation port connection at its

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9

proximal end, said ring being a moulded product of relatively thin and softly pliant elastomeric material, said ring including within the inner periphery of said annulus an apertured panel or membrane establishing separation between a pharyngeal-chamber side and a laryngeal-chamber side, said ring further integrally including at its distal end a distally open tubular conduit for operative engagement and communication with the oesophageal inlet, said tubular conduit extending from its distally open end and in the proximal direction adjacent said panel and on the pharyngeal side of said panel;

a domed backing-plate member of relatively stiff elastomeric material and having a concave side which terminates in a generally elliptical footing in a geometric plane and in sealed engagement with said panel at the inner periphery of said annulus, said backing-plate member having an airway-tube connecting formation on a proximally directional axis that is at an acute angle with said geometric plane, said backing-plate member providing stability to the inner periphery of said annulus and directional stability for said tubular conduit;

an airway tube connected to said connecting formation; and

a gastric-discharge tube connected to said tubular conduit.

2. The mask construction of claim 1, in which said airway tube and said gastric-discharge tube are bonded to each other in side-by-side relation.

3. The mask construction of claim 1, in which said tubular conduit extends proximally to approximately 50 percent of the longitudinal extent of said inflatable ring.

4. The mask construction of claim 1, in which said tubular conduit extends proximally to at least 50 percent of the longitudinal extent of said inflatable ring.

5. The mask construction of claim 1, in which said backing-plate member is formed for directionally guiding relation to said tubular conduit, to determine a straight proximal direction of said tubular conduit for substantially the distal half of the longitudinal extent of said mask.

6. The mask construction of claim 5, in which said backing-plate member is further formed for tubular-conduit guidance on generally a helical arc to a location of gastric-discharge tube entry to said mask alongside said airway tube.

7. The mask construction of claim 1, further including an inflatable back cushion comprising a panel of softly compliant elastomeric material bonded peripherally to the pharyngeal-chamber side of said annulus and extending over said tubular conduit.

8. The mask construction of claim 7, in which said back-cushion panel is peripherally bonded to said tubular conduit.

10

9. The mask construction of claim 8, in which said back-cushion bond to said tubular conduit extends for substantially the distal half of the longitudinal extent of said inflatable ring.

10. The mask construction of claim 8, in which (a) a first arcuate circumferential fraction of said tubular conduit is connected to said backing-plate member, (b) the bond of said back cushion to said tubular conduit is angularly spaced from and generally opposite the connection of said tubular conduit to said backing-plate member, the bond to said back cushion being over a second arcuate circumferential fraction of said tubular conduit, (c) the arcuate circumferential extent by which said angular tubular-member connections are made to said backing-plate member and to said back cushion being reinforced with circumferentially arcuate stiffener formations.

11. The mask construction of claim 10, in which said stiffener formations are arcuate ribs in axially spaced array.

12. The mask construction of claim 11, in which said ribs project radially outward of said tubular conduit.

13. A laryngeal mask construction for concurrent airway service to a patient's laryngeal inlet and for removal of gastric-discharge products from the oesophagus, said construction comprising:

an inflatable/deflatable ring in the form of a generally elliptical annulus having an outer periphery configured for continuously sealed adaptation to the laryngeal inlet, said ring being a moulded product of relatively thin and softly pliant elastomeric material, said ring integrally including at its distal end a distally open tubular conduit through a distal opening in said ring, said distally open tubular conduit being for operative engagement and communication with the oesophageal inlet;

a backing-plate member of relatively stiff elastomeric material having a concave front side which is adapted to face the laryngeal inlet and which terminates in an elliptical footing in a geometric plane and in peripherally sealed engagement with the inner periphery of said inflatable/deflatable ring, said backing-plate member having an airway-tube connecting formation on a proximally directional axis that is at an acute angle with said geometric plane, said backing-plate member having a lumen for airway-tube communication with the laryngeal inlet, and said backing-plate member providing stability to the inner periphery of said annulus and proximally directed directional stability for said tubular conduit;

an airway tube connected to said connecting formation; and

a gastric-discharge tube connected to said tubular conduit.